

**INGREDIENTS:** Black Cohosh (Powd. Ext. Cimicifuga) 0.0065 Gm. Wind Flower (Powd. Ext. Pulsatilla) 0.0065 Gm. Ferrous Sulfate U.S.P. Manganese Dioxide Thiamine Hydrochloride U.S.P. (Vit. B<sub>1</sub>) 0.001 Gm."; and (front panel "½ OUNCE Rem-Al Emetic Brand of Fluid Extract of Ipecac-Alcohol 30% Distributed by REM-AL DRUG CO. 2 SUFFOLK STREET NEW YORK 2, N.Y."; (back panel) "DIRECTIONS Put 15 to 20 drops of REM-AL in a large drink of alcoholic beverage. Half hour later give a small drink using 15 to 20 drops of Rem-Al. NOTE: Use only as directed above and by directions accompanying bottle. CAUTION: Do not use in heart, liver, kidney, circulatory diseases, pregnancy, stomach ulcers, high blood pressure or serious disorder without consulting your physician."

**CHARGE:** 502(a)—the labeling of the articles contained false and misleading representations that the *Quik-Kap capsules* were an adequate and effective treatment for delayed or irregular menstruation, and that the *Rem-Al Emetic* was an adequate and effective treatment for drunkenness; and 502(j)—the *Rem-Al Emetic* was dangerous to health when used in the dosage prescribed, recommended, and suggested in its labeling.

**PLEA:** Guilty.

**DISPOSITION:** 1-15-60. \$1,000 fine, suspended sentence of 90 days in jail, and probation for 1 year.

#### NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

**6002. Grisovin tablets (2 seizure actions).** (F.D.C. Nos. 43172, 43194. S. Nos. 56-794 P, 56-803 P.)

**QUANTITY:** 3 1,000-tablet btls. at Miami, Fla.

**SHIPPED:** Between 4-27-59 and 5-4-59, from New York, N.Y., by Overseas Pharmaceutical Co.

**LABEL IN PART:** "Grisovin 250 Mg. Griseofulvin Glaxo Laboratories, Greenford, England."

**LIBELED:** 6-19-59 and about 6-25-59, S. Dist. Fla.

**CHARGE:** 505(a)—the article was a new drug which may not be introduced or delivered for introduction into interstate commerce, since an application filed pursuant to law was not effective with respect to such drug.

**DISPOSITION:** 8-17-59. Default—destruction.

**6003. Vitamin B<sub>12</sub> injection.** (F.D.C. No. 40930. S. No. 67-040 M.)

**QUANTITY:** 144 10-cc. vials at Baltimore, Md.

**SHIPPED:** 9-18-57, from Chicago, Ill., by Maizel Laboratories, Inc.

**LABEL IN PART:** "Intramuscular 10 cc Intravenous VITAMIN B<sub>12</sub> INJECTION Cyanocobalamin U.S.P. 1000 mcg. Each cc. contains a sterile solution of 1000 micrograms Vitamin B<sub>12</sub> U.S.P. (Cyanocobalamin) in normal saline with 2% Benzyl Alcohol as preservative. \* \* \* 28590."

**RESULTS OF INVESTIGATION:** Examination showed that each cubic centimeter of the article contained 1,039 micrograms of cyanocobalamin (vitamin B<sub>12</sub>), 9.88 milligrams of sodium chloride, and a quantity of unidentified dissolved material.

**LIBELED:** 11-1-57, Dist. Md.

**CHARGE:** 501(b)—when shipped, the quality and purity of the article fell below the standard for *cyanocobalamin injection* set forth in the United States